REMARKS

Claims 1-17 are pending in the instant application. Claims 6, 10-14, 16 and 17 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 1-5, 7-9 and 15 have been rejected. Claims 1 and 15 have been amended. Support for these amendments is provided in the specification at page 14, line 6 and page 14, line 21, through page 16, line 14. Thus, no new matter has been added and entry of these amendments is respectfully requested. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed April 8, 2003. Thus, in an earnest effort to advance the prosecution of this case, Applicants have canceled non-elected claims 6, 10-14 and 16-17, without prejudice. Further Applicants have amended claims 1 and 15 to delete reference to non-elected subject matter. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 112, second paragraph

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that the phrase "selectively hybridizes" in claims 1-5, 7-9 and 15 is not clear because it is not clear what is meant by "selectively hybridizes".

Thus, in an earnest effort to advance the prosecution and in accordance with the Examiner's suggestion to specify the specific conditions, Applicants have amended the claims to state that the nucleic acid molecule selectively hybridizes under stringent hybridization conditions. Stringent hybridization conditions are defined in the specification at page 14, line 21, through page 16, line 14. Thus, the claims as amended, when read in light of the specification, as required by MPEP § 2173, are clear and definite with respect to what is meant by selectively hybridizing.

Withdrawal of this rejection under 35 U.S.C. § 112, second paragraph, is therefore respectfully requested.

III. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 101 as the Examiner suggests that the claimed invention is not supported by either a substantial asserted utility or a well established utility. Claims 1-5, 7-9 and 15 have also been rejected under 35 U.S.C. § 112, first paragraph, as the Examiner suggests that since the claimed invention is not supported by either a substantial asserted utility or a well-established utility, one skilled in the art would not know how to use the claimed invention.

Applicants respectfully traverse these rejections.

At the outset, Applicants respectfully point out that the Examiner's suggestion that the specification is silent as to any teachings, results or correlations between the claimed nucleic acid (SEQ ID NO:27) and prostate cancer is incorrect and contradictory of the Examiner's acknowledgment in this Office Action that the specification states that the "high level of tissue specificity, plus mRNA overexpression in matching samples are indicative of SEQ ID NO:1 through 112 being diagnostic markers for cancer." The range of SEQ ID NO:s specifically

markers for cancer based upon mRNA expression levels is inclusive of SEQ ID NO:27. Further, it is explicitly taught that these nucleic acid molecules are overexpressed in matching samples, which as taught in the specification are cancer samples and the isogenic normal adjacent tissue from the same individual. Thus, the specification does provide a correlative or causal relationship between expression of the claimed nucleic acid molecule and the disease which the Examiner suggests is required to establish a utility in diagnosis of a disease.

Further, the case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980). Clearly identification of SEQ ID NO:27 as overexpressed in cancer tissue constitutes a pharmacological activity relevant to the asserted use as a diagnostic for cancer, thus satisfying the utility requirement.

A specific or substantial utility is one wherein the utility is "credible" to one of skill in the art. In accordance with MPEP § 2107.02, an assertion is "credible" unless (A) the logic

upon which the assertion is based are inconsistent with the logic underlying the assertion. In the instant application, the logic underlying the assertion of utility is neither flawed nor based on facts inconsistent with the logic underlying the assertion. Instead, it is based upon a finding that SEQ ID NO:27 is overexpressed in cancer samples versus normal tissue.

Thus, since the instant specification provides a specific and substantial utility for SEQ ID NO:27 supported by logic and facts consistent with this logic, the instant specification meets the utility requirements as set forth in 35 U.S.C. § 101 and the enablement requirements for use as set forth in 35 U.S.C. § 112, first paragraph.

Withdrawal of these rejections is therefore respectfully requested.

IV. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 112, first paragraph - Written Description

Claim 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner suggests that Applicants have not identified sufficient, relevant,

identifying characteristics, wherein a person skilled in the art would recognize that the inventor had possession of the claimed invention. While adequate description of SEQ ID NO:27 has been acknowledged, the Examiner suggests that this disclosure of a single species does not provide an adequate written description and is not representative of the broadly claimed genus encompassed by nucleic acids having at least 60% identity to SEQ ID NO:27 and nucleic acid molecules that selectively hybridize to SEQ ID NO:27.

Accordingly, in an earnest effort to advance the prosecution of this case and in accordance with the Examiner's suggestion, Applicants have amended the claims drawn to % identity to recite functional language. In particular, claim 1(d) has been amended to recite that the nucleic acid molecule has at least 80% sequence identity to the nucleic acid molecule of (a) or (b) and encodes a prostate specific protein comprising SEQ ID NO:135. Support for this amendment can be found in the specification at page 14, line 6, and in Example 1.

Further, with respect to nucleic acid molecules that selectively hybridize to SEQ ID NO:27, Applicants have amended the claims in accordance with teachings at page 14-16 to specify

hybridization occurs.

With respect to the Examiner's request that Applicants specify whether SEQ ID NO:27 is a full length cDNA, multiple ESTs support SEQ ID NO:27 being approximately the full length gene.

Applicants believe that the pending claims as amended, which are clearly supported by the specification, set forth definitive structural features of the claimed nucleic acid molecules so that one of skill in the art can predictably identify the encompassed molecules as being identical to those now claimed. Further, the claims as amended describe distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention. See MPEP § 2163.02. Thus, the claims as amended meet the written description requirements of 35 U.S.C. § 112, first paragraph.

Withdrawal of this rejection is therefore respectfully requested.

V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

/Kathleen A. Tyrrell/

Kathleen A. Tyrrell
Registration No. 38,350

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Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515